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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|-------------------------|------------------|
| 10/027,593 | 10/25/2001 | Douglas A. Collins | COP1008US | 6800 |
| 20786 | 7590 | 12/15/2004 | EXAMINER | |
| KING & SPALDING LLP 191 PEACHTREE STREET, N.E. ATLANTA, GA 30303-1763 | | | MCINTOSH III, TRAVISS C | |
| | | ART UNIT | PAPER NUMBER | |
| | | 1623 | | |

DATE MAILED: 12/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/027,593 | COLLINS ET AL. | |
| | Examiner | Art Unit | |
| | Traviss C McIntosh | 1623 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
 THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 02 September 2004.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 15-28 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-11 is/are rejected.
- 7) Claim(s) 12-14 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 25 October 2001 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date _____.
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I in the reply filed on September 2, 2004 is acknowledged. Moreover, Group XI drawn to the compositions comprising the compounds of Group I will be examiner together with Group I.

Additionally, the species election previously set forth by the examiner has hereby been withdrawn, as the species was not located by the examiner.

An action on the merits of claims 1-14 is contained herein below.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code, see page 3, lines 13-14. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Objections

Claim 4 is objected to because of the following informalities: the claim ends in a semicolon rather than a period. Appropriate correction is required.

Claims 12-14 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from another multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims 12-14 have not been further treated on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The inclusion of arrows and the associated letters a-g on the amidoalkyl groups of claim 1 is confusing as it is unclear if applicants intend these to be patentable limitations or merely markers for the amidoalkyl groups.

Claims 1 is indefinite wherein the inclusion of parenthetical phrases leaves ambiguity and uncertainty as to whether the contents inside the parenthesis are intended as being that which applicant intends as their invention. For example, lines 2-3 and 5-6 of the second page of claim 1. Clarity is respectfully requested. Removal of parentheses will obviate this rejection.

The phrase “of a singular molecular weight”, in subset (xi) of claim 1, while defining L, is indefinite. It is unclear as to what is intended by a moiety which has a “singular molecular weight”. Clarity is respectfully requested.

The phrase “and that does not significantly impair the ability of the TC- or IF-binding carrier to bind to a transcobalamin receptor, optionally when bound to a transport protein” is indefinite. It is unclear as to what would be “significantly impaired” would be. Moreover, it is unclear how the function of the linker can be used to define the actual moiety of the L group. One of skill in the art would not be able to know the metes and bounds of the claim without

further experimentation as it is not clear as to what linkers would, and what linkers would not impair the ability of the TC- or IF-binding carrier to bind to the receptor.

Claim 1 recites the limitation “at least one of Y, R, G, E, K, M, and V” in subset (xix). There is insufficient antecedent basis for this limitation in the claim. It is noted that Y¹, Y², Y³, etc. do not provide antecedent basis for Y, without the numerical indicator, as R¹, R², R³, etc., do not provide proper antecedent basis for R, etc.

Claim 5 is confusing as the claim provides that “at least one –L-T is independently a poly(amino acid) residue bound to one or more T”. Is –L-T intended to be bound to a T moiety which is already included on the compound? Or is the “poly(amino acid) residue” only defining L? Clarity is respectfully requested.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by Russell-Jones et al. (US 6,262,253).

Russell-Jones et al. disclose a vitamin B12 analogue complexed to either GPX or EPO that retain affinity for IF. There is a spacer included to link the therapeutic to a functional group on the

vitamin B12 analogue. It is noted that applicant's compound is drawn to a multitude of various vitamin B12 analogues, and requires that at least one of the various R groups (or Y, G, E, K, M, or V groups) is not as it is found in natural vitamin B12. Many of these can merely be the next highest homolog, which would at the minimum be obvious over the '253 patent. Moreover, it is noted that since the Office does not have the facilities for preparing the claimed materials and comparing them with prior art inventions, the burden is on Applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980).

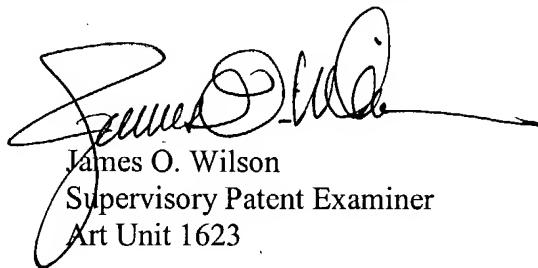
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Traviss C McIntosh whose telephone number is 571-272-0657. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Traviss C. McIntosh
December 11, 2004



James O. Wilson
Supervisory Patent Examiner
Art Unit 1623